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EXAMINER

EVOY, NICHOLAS LANE

ART UNIT	PAPER NUMBER
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3768

NOTIFICATION DATE	DELIVERY MODE
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04/21/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/560,217	Applicant(s) YANOF ET AL.	
	Examiner NICHOLAS L. EVOY	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 1-18 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 1 and 10 recite the limitation "the associated imaging device". There is insufficient antecedent basis for this limitation in the claim. For the purposes of examination the claim will be interpreted to mean the aforementioned imaging device.
4. Claim 1 recites the limitation "along a selected linear path" in lines 17-18. There is insufficient antecedent basis for this limitation in the claim. For the purposes of examination the claim will be interpreted to mean "along said linear path".
5. Claims 2-9 and 11-18 rejected as being dependent from independent claims 1 and 10.

35 USC § 112 6th Paragraph

6. Claims 10-18 are presumed to invoke 35 USC 112 6th Paragraph because the claims meet the following three-prong analysis:
 - a. The claim limitations must use the phrase "means for" or "step for";
 - b. The "means for" or "step for" must be modified by functional language; and

Art Unit: 3768

- c. The phrase “means for” or “step for” must not be modified by sufficient structure, material or acts for achieving the specified function (See MPEP 2181).
7. In this case, the Examiner has interpreted the “means for” function of Claims 10-18 (line 7) to relate to: “means for selecting a virtual trajectory defining a path for inserting the medical device into said patient” as referenced on Pages 9-12 (i.e. virtual planning) of applicant’s specification.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 1-20 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims encompass a human and living subject matter, which is not a result of human intervention, and therefore is not patentable subject matter (See MPEP 2105).
10. Regarding claim 1, the claim recites "a patient" as a component in the system claim multiple times (see lines 1, 2, 3, 5, 7 and 17) as well as positively reciting "the associated human operator" in lines 19-20.
11. Regarding claim 10, the claim recites “a patient” as a component in the method claim multiple times (see lines 1, 3, 4, 8, 12, 19 and 24) as well as positively reciting “an associated operator” and “an associated human operator” in lines 17-18 and 21-22.
12. Regarding claim 19, the claim recites “a patient” as a component in the apparatus claim at line 10, as well as positively reciting "an operator" at lines 8 and 12.

Art Unit: 3768

13. Claims 2-9, 11-18 and 20 are rejected as being dependent from claims 1, 10 and 19, respectively.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 1-8, 10-17 and 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Kwoh et al, US Patent Number 5,078,140 in view of McIntyre, IV, US patent Number 6,468,226 B1.

16. In re claims 1, 10 and 19, Kwoh discloses a system, method or apparatus for inserting a medical device into a patient including an imaging device scanning the patient to generate a volumetric image data set of the patient, a human readable device for displaying an image of the patient derived from the volumetric image data set, means for selecting a virtual trajectory defining a path for inserting the medical device into the patient, robotic means on the imaging device and movable into selected positions relative to the imaging device, and a guide apparatus disposed on the robotic means to direct movement of the medical device relative to the patient disposed on the robotic means, the guide apparatus comprising: a connector portion coupling the guide apparatus with the associated imaging device at a distal end of the robotic means (from column 2, line 62 to column 3, line 9); a main body portion supported relative to the

Art Unit: 3768

associated imaging device by the connector portion (see Figs. 1, 4 and 5); a gripping area formed at a first end of the main body portion, the gripping area adapting the guide apparatus for manual gripping by an associated operator (i.e. when the disclosed robotic system is in a mode for manual surgical operation; see column 6, line 57 to column 7, line 2); and, a holding area formed at a second end of the main body portion, the holding area holding the medical device in an orientation suitable for motion relative to the patient along a selected linear path, the guide apparatus being operative to translate the medical device along the selected linear path in response to manual force applied by the associated human operator at the gripping area (see from column 5, line 17 to column 10, line 4).

17. Kwoh does not disclose that the medical device is comprises a linear slider mechanism which restricts movement of the guide apparatus such that it is translated along a linear path in response to manual force applied by the associated human operator at said gripping area during insertion of the medical device. McIntire teaches a remote tissue biopsy apparatus that inserts and slides a biopsy needle along a linear trajectory in response to a manual force applied by a human operator at a knob (Column 8, Lines 53-65, Column 10, Lines 23-40 and Figures 1 and 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Kwoh and McIntyre because linear insertion of the device during the medical procedure increases accuracy of the procedure in cases where the insertion site is not visible to the technician (McIntyre: Column 1, Lines 58 - Column 2, Lines 11).

Art Unit: 3768

18. In re claims 2 and 11, Kwoh discloses that the imaging device is a CT scanner, an MRI scanner, a CCT scanner, a fluoroscope, a SPECT scanner, a PET scanner, or a combination of the foregoing (i.e. for specific use in CT, MRI, ultrasound or PET imaging; see column 2, lines 61-68).

19. In re claims 3 and 12, Kwoh discloses that the medical device is an ablation probe or a biopsy needle (i.e. using the system for a needle biopsy surgery; see column 9, lines 6-12).

20. In re claims 4 and 13, Kwoh discloses that the means for selecting the virtual trajectory includes means for selecting a virtual target point in the image of the patient by identifying a first coordinate in the image of the patient, and means for identifying a virtual path extending from the selected virtual target point and out from the body of the patient (i.e. utilizing stereotactic software for use with a CT scanner and interfacing with a robotic arm for surgeon interaction; see column 6, line 5-23).

21. In re claims 5 and 14, Kwoh discloses that the robotic means is adapted to move the guide apparatus into a position whereat the medical device is in an orientation suitable for motion relative to the patient along the selected linear path coincident with the virtual path extending from the virtual target point and out from the body of the patient (i.e. a system that moves linearly in line with a predetermined surgical path; see column 5, line 23 to column 6, line 23).

22. In re claims 6 and 15, McIntire teaches a remote tissue biopsy apparatus which includes a linear slide mechanism that inserts and slides a biopsy needle along a linear

Art Unit: 3768

trajectory in response to a manual force applied by a human operator at a knob (Column 8, Lines 53-65, Column 10, Lines 23-40 and Figures 1 and 2).

23. In re claims 7 and 16, Kwoh discloses that the position feedback device provided on the connector portion of the guide apparatus for providing a feedback signal indicating a position of the guide apparatus relative to the patient (i.e. encoders present that provide position and velocity feedback; see column 4, lines 1-6) and means for displaying an image of the medical device as it is physically moved relative to the patient based upon feedback signal, together with the image of the patient and the virtual path (i.e. the N-shaped locators that provide spatial position references that show up in cross-sectional images obtained by operating the CT scanner; see column 6, lines 24-40).

24. In re claims 8 and 17, Kwoh discloses that the holding area is formed of an x-ray transmissive material (i.e. the N-shaped locators that provide spatial position references that show up in cross-sectional images obtained by operating the CT scanner; see column 6, lines 24-40).

25. Claims 9, 18 and 20 rejected under 35 U.S.C. 103(a) as being unpatentable over Kwoh et al, US Patent Number 5,078,140 in view of McIntyre, IV, US Patent Number 6,468,226 B1 as applied to claims 1-8, 10-17 and 19 above, and further in view of Johnson, US Patent Number 3,893,813.

26. Regarding claims 9, 18 and 20, Kwoh and McIntyre teach an imaging device and surgical method and apparatus as referenced above. Kwoh and McIntyre do not disclose that the holding area includes a set of tweezers-like arm portions adapted to

Art Unit: 3768

grip the medical device in a V-shaped groove formed by the arm portions. Johnson teaches using a clamp with tweezers-like arm portions for use with chemical equipment in a laboratory setting, such as with pipettes and other precision instruments (see from column 1, line 64 to column 2, line 33 and Figures 1-3 and 6). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system, method or apparatus of Kwoh and McIntyre with the feature of a set of tweezers-like arm portions of the medical device holding mechanism as taught by Johnson as Kwoh and McIntyre and Johnson are directed to the system, method or apparatus for inserting a medical device into a patient, so as to give a sure way for mounting medical devices to the surgical system while still preserving the accuracy of the device and the sturdiness of the mount.

Response to Arguments

27. Applicant's arguments filed 10/25/10 have been fully considered but they are not persuasive.

28. Regarding applicant's argument that "McIntyre, however, does not disclose a connector portion coupling the guide apparatus with the associated imaging device and comprising a linear slider mechanism which restricts movement of the guide apparatus to a single linear path during insertion of a medical device by manual force. Rather, McIntyre discloses that a user may depress a trigger 38 to move a drive chain 43 and therefore a reciprocating driving conveyor 22":

This is one limited embodiment of the teaching of McIntyre. As currently presented, applicant's claim defines "the guide apparatus being operative to translate the medical device along said selected linear path in response to manual force applied by the associated human operator at said gripping area during insertion of the medical device as restricted by the linear slider mechanism" (Claim 1, Lines 18-21). McIntyre teaches "use of a manually accessible know, for example, operatively connected to gear 42, or multiple gears is desirable because it provides force feedback sensation to medical personnel, allowing a better "feel" for the tissue through which tissue collection cannula 26 is travelling. In addition to actuating trigger 38 effecting the movement of drive chain 43 disclosed herein, mechanisms utilized to drive the movements of reciprocating driving conveyor 22 can also include, but not be limited to, other mechanical, electric, hydraulic, and pneumatic means coupled to levers, gears, rods, clutches, belts and linkages..." (Column 10, Lines 29-41). The teaching of McIntyre clearly reads on applicant's claim language. Additionally, even if the trigger mechanism embodiment of McIntyre was to be considered, the disclosure would still read on applicant's claim as the translation of the needle along the path is a result of the manual force applied by the associated human operator to the trigger mechanism.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICHOLAS L. EVOY whose telephone number is

Art Unit: 3768

(571)270-1388. The examiner can normally be reached on M-F 7:30-5:00, Alternating Fridays Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NICHOLAS L. EVOY/
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768